

Docket No.: 64395(70904)  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

---

In re Patent Application of:  
Kazuhisa Sugimura et al.

Application No.: 10/555,074

Confirmation No.: N/A

Filed: October 28, 2005

Art Unit: N/A

---

For: HUMAN ANTI-HUMAN INTERLEUKIN-18  
ANTIBODY, FRAGMENT THEREOF, AND  
METHOD FOR USING SAME

---

Examiner: Not Yet Assigned

**INFORMATION DISCLOSURE STATEMENT (IDS)**

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 CFR 1.97(b)(3)).

Applicant has not submitted copies of each cited U.S. patent and U.S. patent application as required by 37 CFR 1.98(a)(2)(i), amended October 2004, as the U.S. Patent and Trademark Office has waived this requirement for all U.S. patent applications. Applicant submits herewith copies of foreign and non-patents in accordance with 37 CFR 1.98(a)(2).

RECEIVED  
FEB 21 2006

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 04-1105, under Order No. 64395(70904). A duplicate copy of this paper is enclosed.

Dated: February 15, 2006

Respectfully Submitted,

By 

Jonathan M. Sparks, Ph.D.

Registration No.: 53,624

EDWARDS ANGELL PALMER & DODGE  
LLP

P.O. Box 55874

Boston, Massachusetts 02205

(617) 439-4444

Attorneys/Agents For Applicant

Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/555,074
				Filing Date	October 28, 2005
				First Named Inventor	Kazuhisa Sugimura
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	1	of	1	Attorney Docket Number	64395(70904)

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	AA	US-2002/0128450 A1	09/12/02		

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	BA	WO-2000/56771 A1	09/28/00			
	BB	JP-2000-236884 (A)	09/05/00			

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	CA	Haruki OKAMURA et al., "Cloning of a New Cytokine that Includes IFN- $\gamma$ Production by T cells", Nature, Vol. 378:88-91 (2 November 1995)	
	CB	Tomohiro YOSHIMOTO et al., "Interleukin 18 together with Interleukin 12 Inhibits IgE Production by Induction of Interferon- $\gamma$ Production from Activated B Cells", Proc. Natl. Acad. Sci. USA, Vol. 94:3948-3953 (April 1997)	
	CC	Kenji NAKANISHI et al., "Interleukin-18 Regulates Both TH1 and TH2 Responses", Annu. Rev. Immunol. 19:423-474 (2001)	
	CD	Tomohiro YOSHIMOTO et al., "IL-18, Although Antiallergic When Administered with IL-12, Stimulates IL-4 and Histamine Release by Basophils", PNAS, 96(24):13962-13966(November 23, 1999)	
	CE	Tomohiro YOSHIMOTO et al., "IL-18 Induction of IgE: Dependence on CD4 <sup>+</sup> T cells, IL-4 and STAT6", Nature Immunology, 1(2):132-137 (August 2000)	
	CF	Tomohiro YOSHIMOTO et al., "Nonredundant Roles for CD 1 d-Restricted Natural Killer T Cells and Conventional CD4 <sup>+</sup> T Cells in the Induction of Immunoglobulin E Antibodies in Response to Interleukin 18 Treatment of Mice", The Journal of Experimental Medicine, 197(8):997-1005 (April 21, 2003)	
	CG	Hiroshi KONISHI et al., "IL-18 Contributes to the Spontaneous Development of Atopic Dermatitis-Like Inflammatory Skin Lesion Independently of IgE/stat6 under Specific Pathogen-Free Conditions", PNAS, 99(17):11340-11345 (August 20, 2002)	
	CH	Yong GU et al., "Activation of Interferon- $\gamma$ Inducing Factor Mediated by Interleukin-1 (3 Converting Enzyme", Science, 275: 206-209 (10 January 1997)	
	CI	Kei-ichi YAMANAKA et al., "Skin-Specific Caspase-I-Transgenic Mice Show Cutaneous Apoptosis and pre-Endotoxin Shock Condition with a High Serum Level of IL-18", The Journal of Immunology, pp.997-1003 (2000)	
	CJ	Kiyoshi TAKEDA et al., "Essential Role of Stat6 in IL-4 Signalling", Nature, 380(6575):627-630(18 April 1996)	

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

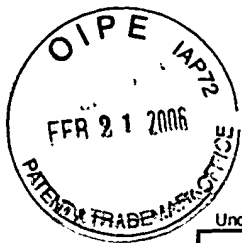
Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/555,074
				Filing Date	October 28, 2005
				First Named Inventor	Kazuhisa Sugimura
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	2	of	1	Attorney Docket Number	64395(70904)

CK	Hiroko TSUTSUI et al., "IL-18 Accounts for Both TNF- $\alpha$ - and Fas Ligand-mediated Hepatotoxic pathways in Endotoxin-Induced Liver Injury in Mice", The Journal of Immunology, pp.3961-3967(1997)	
CL	Hiroko TSUTSUI et al., "Caspase-1-Independent, Fas/Fas Ligand-Mediated IL-18 Secretion from Macrophages Causes Acute Liver Injury in Mice", Immunity, 11:359-367 (September 1999)	
CM	Hiroko TSUTSUI et al., Pathophysiological Roles of Interleukin-18 in Inflammatory Liver Diseases", Immunological reviews, 174:, 192-209 (2000)	
CN	Shau-ping LEI et al., "Characterization of the <i>Erwinia carotovora pelB</i> Gene and its Product Pectate Lyase", Journal of Bacteriology, pp. 4379-4383 (September 1987)	
CO	Takahiro FUKUMOTO et al., "Peptide Mimics of the CTLA4-Binding Domain Stimulate T -Cell Proliferation", Nature Biotechnology, 16:267-270 (March 1998)	
CP	Takaaki SUGIMOTO et al., "Interleukin 18 Acts on Memory T Helper Cells Type 1 to Induce Airway Inflammation and Hyperresponsiveness in a Naive Host Mouse", J. Exp. Med., 199(4):535-545 (February 16, 2004)	
CQ	Henry MILGROM, et al., "Treatment of Allergic Asthma with Monoclonal Anti-IgE Antibody", the New England Journal of Medicine, 341(26):1966-1973 (December 23, 1999)	
CR	James D. MARKS et al., "By-passing Immunization Human Antibodies from V -gene Libraries Displayed on Phage", J. Mol. Biol., 222:581-597 (1991)	
CS	Kouji TOMINAGA et al., "IL-12 Synergizes with IL-18 or IL-1 (3 for IFN- $\gamma$ Production from human T Cells", International Immunology, 12(2):151-160 (2000)	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--



PCT

PTO/SB/92 (09-04)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Application No. (if known): 10/555,074

Attorney Docket No.: 64395(70904)

## Certificate of Mailing under 37 CFR 1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to:

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

on February 15, 2006  
Date



Signature

Sharon Bizokas

Typed or printed name of person signing Certificate

@@@

Registration Number, if applicable

(617) 439-4444

Telephone Number

Note: Each paper must have its own certificate of mailing, or this certificate must identify each submitted paper.

Information Disclosure Statement (2 pages)  
Form PTO/SB/08 (22 References) (2 pages)  
Return Receipt Postcard